UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,583	04/18/2005	Peter Kraass	C048549/0180225	1415

7590 04/26/2007

Stephen M Haracz
Bryan Cave
1290 Avenue of the Americas
New York, NY 10104-3300

EXAMINER	
WEDDINGTON, KEVIN E	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,583	KRAASS, PETER	
	Examiner	Art Unit	
	Kevin E. Weddington	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9-3-04; 12-6-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claims 1-33 are presented for examination.

Applicant's drawings, preliminary amendment and information disclosure statement filed September 3, 2004; and the information disclosure statement filed December 6, 2004 have been received and entered.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a written description rejection.

Claims 1-33 described active ingredients that lower the cholesterol level in the blood. The instant claims cover all active ingredients compounds having the pharmaceutical property of lowering the cholesterol levels in the blood. Describing an active ingredient by its functions will not substitute for written description of the

structure of the compound. The invention should be described in such a way as to described what the invention is, not what the invention does. Describing the function of a compound fails to distinguish the compound from other molecules or agents that can perform the same functions.

Undue experimentation is a conclusion reaches by weighing the noted factual considerations set forth below as seen in In re Wands, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1401 (Fed. Cir. 1988). A conclusion of lack of enablement means that, based on the evidence regarding a fair evaluation of an appropriate combination of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

The factors include:

1) the quantity of experimentation necessary

2) the amount of direction or guidance provided

3) the presence or absence of working examples

4) the nature of the invention

5) the state of the art

6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice that instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

Claims 1-33 are directed to active ingredients that lower the cholesterol levels in blood. The instant claims cover all active ingredients having pharmaceutical property of being known as a compound to lower cholesterol levels. Although claims 2, 10, 24 and 30-33 lists specific examples of active ingredients which are alleged to have the property to lower cholesterol levels in blood, and claims 1, 10, 24 and 30-33 are directed to a variety of active ingredients with the functional description of being known as an active ingredient which is alleged to have the property to lower cholesterol levels in blood.

The instant claims are very broad. For instance, claim 1 is to a plethora of compounds of as described by the functional properties as being known to lower cholesterol levels in blood.

The relative skill of those in the art is generally that of a Ph.D. or M.D.

One skilled in the art would not predict from the instant disclosure which active ingredients would fall under the umbrella of functional description of being known as broadly as cholesterol inhibitor. IN fact, the courts have made a distinction between mechanical elements function the same in different circumstances, yielding

predictable results, chemical and biological compounds often react unpredictably under different circumstances.

The breadth of the claims

The claims are very broad and inclusive to all active ingredients that lower cholesterol levels in blood.

The amount of direction or guidance provided and the presence or absence of working examples

The working examples only show fluvastatin, as the active ingredient, which lowers the cholesterol level in the blood.

No examples showing the other active ingredients, which lower the cholesterol levels in the blood.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to how the skilled artisan would be able to extrapolate from the disclosure and examples provided to make and possibly use the claimed invention. The amount of guidance or direction needed to enable the invention is inversely related to the degree of predictability in the art. Thus, although a single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements, in cases involving unpredictable factors, such as most chemical reactions and physiological activity, more teaching or guidance is required. (In re Fischer, 427 F. 2d 839, 166 USPQ 24; Ex Parte Hitzeman, 9 USPQ 2d 1823).

The quantity of experimentation needed to be performed by one skilled in the art is yet another factor involved in the determining whether "undue experimentation" is required to make and use the instant invention. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if its is merely routine, or of the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. For these reasons, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study" to determine all the active ingredients or agents that are broadly known to possess the property of lowering cholesterol levels in the blood as described in this specification. In view of the information set forth supra, the instant disclosure is not seen to be sufficient to describe the use of any compound , which is regarded as the functional description of an active ingredient for lowering cholesterol levels in the blood.

Therefore, undue experimentation would be required to practice the invention as it is claimed in its current scope.

Claims 1-33 are not allowed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Ayer et al. (4,915,954).

Ayer et al. teach a dosage form delivering a drug at two different rates such as a first or fast releasing layer and a second or short releasing layer that are delivered through the exit means over two different periods of time (See the abstract). Note particular column 16, claim 3 discloses a dosage form for delivering a drug orally to an animal, wherein the first release layer is an ingredient that lowers the cholesterol level in blood (pravastation, lovastatin, simvastatin and fluindostatin); and the second release layer is an ingredient that lowers the cholesterol level in blood also. Note the various polymers and water-insoluble polymers used to form the instant delivery drug (see column 5, lines 55-68 and column 6, lines 1-68). Column 9, lines 50-54 discloses the amounts of each active ingredients from 0.05 ng to 5 g or more, note the applicant's percent weight amount range of 0% to 5% of first layer and from 6% to 100% of second layer falls within the cited reference ranges. Column 10, lines 32-49 disclose the dosage form can be formulated by two different systems such as dry granules (pellets) and wet granules.

Clearly, the cited reference teaches every limitation of the applicant's instant invention; therefore, the instant invention is unpatentable.

Claims 1-33 are not allowed.

The remaining reference listed on the enclosed PTO-892 is cited to show the state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 12:30 pm-9:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kevin E. Weddington
Primary Examiner
Art Unit 1614

K. Weddington
April 24, 2007